

**Rejections Under 35 U.S.C. §102(b)**

The examiner has rejected claims 1-6 under 35 U.S.C. §102(b) as allegedly anticipated by Bocan et al. (WO 97/16184). This rejection is respectfully traversed.

The examiner has rejected claims 1, 7, and 8 under 35 U.S.C. §102(b) as allegedly anticipated by Bisgaier et al. (U.S. Patent No. 5,648,387). This rejection is respectfully traversed.

The examiner has rejected claims 1-3 and 9-10 under 35 U.S.C. §102(b) as allegedly anticipated by Helms et al. (U.S. Patent No. 5,182,298). This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found in the prior art reference (see, Verdegaal Bros. V. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). The present claims are directed toward a method for preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease and in need of such treatment comprising administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol. The present application discloses that by administering to a patient a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol such patients are less likely to encounter an adverse heart event within the following 18 months as compared to patients who had undergone angioplasty. Furthermore, the present application discloses that by administering to a patient a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol such patients who were originally candidates for angioplasty were able to remain on drug therapy alone without experiencing any adverse cardiovascular events over the following 18 months.

Bocan discloses a combination of an ACAT inhibitor and an HMG-CoA reductase inhibitor effective for lipid regulation. Nowhere in Bocan is it disclosed that catheter-based revascularization in patients suffering from coronary artery disease can be prevented or delayed by administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol. Bocan only discloses that a combination of ACAT inhibitors and HMG-CoA reductase inhibitors can reduce apo B-containing lipoprotein levels to a greater extent than either inhibitor on its own, that a normalization of plasma lipoprotein profile can be

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achieved, and that the histologic character of atherosclerotic lesions is less complicated when the combination is used as opposed to just an HMG-CoA reductase inhibitor.

Bisgaier discloses dialkyl ether compounds having terminal carboxy or tetrazole groups that are useful in lowering certain plasma lipids, including Lp(a), triglycerides, VLDL- and LDL-cholesterol, and elevating others such as HDL-cholesterol. The dialkyl ether compounds disclosed by Bisgaier are also taught to be effective for preventing and treating vascular disease and diabetes. Nowhere in Bisgaier is it disclosed that catheter-based revascularization in patients suffering from coronary artery disease can be prevented or delayed by administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol. Bisgaier only discloses that the subject dialkyl ethers are useful for treating vascular disease by virtue of their ability to lower plasma cholesterol levels of triglyceride-rich lipoprotein such as LDL, and that the disclosed dialkyl ethers are particularly effective at lowering Lp(a) as well as elevating HDL-cholesterol.

Helms discloses a class of 1,2,3,7,8,8a-Hexahydro-naphthalene derivatives useful as cholesterol lowering agents. The 1,2,3,7,8,8a-Hexahydro-naphthalene derivatives disclosed by Helms can also be used in combination with other cholesterol lowering agents, such as HMG-CoA reductase inhibitors. The 1,2,3,7,8,8a-Hexahydro-naphthalene derivatives disclosed by Helms are also taught to be effective antifungal agents. Nowhere in Helms however, is it disclosed that catheter-based revascularization in patients suffering from coronary artery disease can be prevented or delayed by administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol. Helms only discloses that the subject 1,2,3,7,8,8a-Hexahydro-naphthalene derivatives are cholesterol lowering agents useful for *treating hypercholesterolemia not preventing or delaying catheter-based revascularization*.

As Bocan, Bisgaier, and Helms fail to set forth each and every element of pending claims 1-10, withdrawal of the rejections under 35 U.S.C. §102(b) is respectfully requested.

#### **Rejection Under 35 U.S.C. §102(e)**

The examiner has rejected claims 1-8 under 35 U.S.C. §102(e) as allegedly anticipated by Bisgaier et al (WO 99/30704). This rejection is respectfully traversed.

The examiner has rejected claims 1-8 under 35 U.S.C. §102(e) as allegedly anticipated by Whitney et al (U.S. Patent No. 6,180,660). This rejection is respectfully traversed.

As previously stated, a claim is anticipated only if each and every element as set forth in the claim is found in the prior art reference. The present claims are directed toward a method for preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease and in need of such treatment comprising administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol.

Bisgaier discloses pharmaceutical compositions that include a carboxyalkylether, which raises HDL-cholesterol, and a statin, which reduces plasma levels of LDL-cholesterol, that is useful for treating vascular disease and diabetes mellitus. Bisgaier discloses a certain class of carboxyalkylethers on page 3, and a variety of statins on page 26, that may be used in a pharmaceutical composition to treat vascular disease or diabetes mellitus. Nowhere in Bisgaier however, is it disclosed that catheter-based revascularization in patients suffering from coronary artery disease can be prevented or delayed by administering a cholesterol lowering agent in an amount effective to cause an aggressive lowering of LDL cholesterol. Bisgaier only discloses pharmaceutical compositions including the subject carboxyalkylethers in combination with a statin for treating vascular disease or diabetes mellitus.

Whitney discloses a method for preventing or reducing the risk of a first occurrence of a cardiovascular event using an HMG-CoA reductase inhibitor alone or in combination with another lipid altering agent. Whitney also discloses useful HMG-CoA reductase inhibitors such as atorvastatin. Whitney, however, further discloses that subjects to be treated are those having an average serum total cholesterol level, an average to mildly elevated serum LDL-cholesterol level, and a below average serum HDL-cholesterol level, with no history of clinically evident coronary disease. The presently claimed methods are directed toward preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease while Whitney requires that the subject have no history of clinically evident coronary heart disease prior to the initial administration. Therefore, Whitney does not set forth each and every element of the pending claims and, in fact, teaches away from the presently claimed methods.

As Bisgaier, and Whitney fail to set forth each and every element of pending claims 1-10, withdrawal of the rejections under 35 U.S.C. §102(e) is respectfully requested.

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**Rejection Under 35 U.S.C. §112, Second Paragraph**

The examiner has rejected claims 3 and 10 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. This rejection is respectfully traversed.

It is respectfully submitted that claims 3 and 10 are definite and are written in proper Markush form. There is no requirement that the phrase "selected from the group consisting of" be used. Alternative expressions, as used in claims 3 and 10, are permitted if they present no ambiguity with respect to the question or scope or clarity of the claims (see, MPEP 2173.05(h) and In re Gaubert, 187 USPQ 664 (CCPA 1975)).

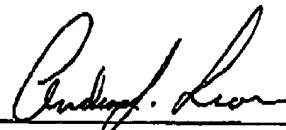
In view of these amendments and remarks, withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

The above discussion and corresponding Amendments are based on section 112 issues and are not made to overcome art-based rejections. Accordingly, such discussion and corresponding Amendments should not be construed in a limiting manner.

It is respectfully submitted that the claims are in condition for allowance. Notification to this affect is earnestly solicited. The Examiner is encouraged to contact the Applicants' undersigned attorney to discuss this matter if any questions should arise upon further examination of the pending claims.

Respectfully submitted,

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